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METHOD AND DEVICE FOR MONITORING THE ACCESS TO THE CARDIOVASCULAR SYSTEM OF A PATIENT

The present invention relates to a method and a
5   device for monitoring the access to the cardiovascular system of a patient undergoing an extracorporeal treatment of blood.

The invention is useful in any kind of treatment in which blood is continuously withdrawn from a
10   patient, circulated and treated in a treatment device, and returned, once treated, to the patient. Hemodialysis, hemofiltration, apheresis and plasmapheresis are examples of such treatment.

For the sake of clarity, the invention will be
15   described hereunder in relation to a specific treatment, hemodialysis, to which however it is not limited as will readily appear to the persons skilled in the art.

A dialysis machine generally comprises.
20   - a filter (hemodialyzer) having a first and a second compartments separated from one another by a semipermeable membrane;

- an extracorporeal blood circuit, having an arterial branch connected to an inlet of the first
25   compartment and a venous branch connected to an outlet of the first compartment; a blood pump is arranged on the arterial line and a bubble trap is connected to the venous line;

- an dialysis liquid circuit, having an fresh
30   dialysis liquid supply branch connected to an inlet of the second compartment and a used liquid branch connected to an outlet of the second compartment.

In use, the blood of the patient and the dialysis liquid are respectively circulated in the first and the
35   second compartments, generally in counterflow.

During a dialysis treatment, undesirable substances (by-products of the metabolism, such as urea, creatinine, etc.) contained in the blood migrate across the semipermeable membrane from the blood

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compartment to the dialysis liquid compartment by
diffusion (dialysis phenomenon, strictly speaking) and
also generally by convection, a fraction of plasma
water being usually filtered during the treatment so
5   that the patient looses a few kilograms (so-called
"weight loss") corresponding to an excess of water
accumulated in the body between two treatment sessions.

Each branch of the extracorporeal circuit is
fitted with a needle (respectively, arterial needle and
10 venous needle), by means of which the extracorporeal
circuit is connected to the patient: just before
starting the treatment, the arterial needle and the
venous needle are inserted in the fistula of the
patient (portion of a vein surgically connected to an
15 artery) for respectively collecting the blood to be
treated and returning the treated blood to the
patient's cardiovascular system.

Disconnection of one of the aforementioned needles
from the fistula causes interruption of access to the
20 patient's cardiovascular system. Disconnection of the
venous needle, if not detected in time, has
particularly serious consequences, as it can cause
exsanguination of the patient. For this reason there
have been various attempts to provide methods capable
25 of detecting disconnection of the needles, and
especially of the venous needle.

One of these methods, which is based on the
electrical conductivity of the blood, is described in
WO 99/12588. According to this method, the
30 extracorporeal circuit and the patient's cardiovascular
system are subjected to an electric current, and
changes in the current that are caused by the
disconnection of one of the needles or both of the
needles is detected, by means of measuring instruments
35 arranged along the extracorporeal circuit. The
measuring instrument used are inductive couplers, i.e.
coils arranged at predetermined locations along the
extracorporeal blood circuit.

The method described above has various drawbacks.
In particular, although valid from the theoretical
standpoint, this method is not able to provide
satisfactory results from the practical standpoint,
5   because the high electrical impedance caused by the
peristaltic pump, which in fact interrupts the
continuity of blood flow, necessitates operating with
relatively high currents in order to make use of the
scant conductivity of the materials of which the
10 extracorporeal circuit, the dialyzer, the hose of the
peristaltic pump and the bubble trap are made (PVC,
polycarbonate). The use of relatively high currents is
certainly not advisable in a machine connected to a
patient and even if they were used, it would not be
15 possible to transmit these high currents by means of an
inductive coupler which, among other things, also
generates parasitic currents which disturb the
measurement. In some dialysis machines the bubble trap
also represents a high impedance of the same order of
20 magnitude as the peristaltic pump, and thus makes one
of the drawbacks previously described even more acute.

Therefore, in view of the fact that it is
advisable to operate with relatively low currents and
that the impedance of the peristaltic pump, and in the
25 majority of cases, of the bubble trap, is high, it
follows that disconnection of one of the needles causes
only slight changes in current, such as could be
confused with the background noise of the measuring
instrument.

30 Furthermore, this method does not take into
account that the patient might be connected to earth
and that the dialyzer itself is in fact connected to
earth, since the dialysis fluid circuit is connected to
earth in accordance with the provisions of the safety
35 standards relating to dialysis machines.

The aim of the present invention is to provide a
method that obviates the drawbacks of the prior art.

According to the present invention, a method is
provided for monitoring the access to the

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cardiovascular system of a patient undergoing an
extracorporeal treatment of blood in a machine
comprising a treatment device and an extracorporeal
circuit having an arterial branch and a venous branch,
5 the arterial branch having a first end fitted with an
arterial needle to be inserted in the vascular system
of the patient and a second end connected to an inlet
of the treatment device, and the venous branch having a
first end connected to an outlet of the treatment
10 device and a second end fitted with an venous needle to
be inserted in the vascular system of the patient,
the method being characterized in that it comprises the
steps of:
• generating a potential difference between a first
15 point of the venous branch and a part of the machine;
• detecting the value (dV) of a quantity that
correlates with the electric current along at least one
section of the venous branch between the first point
(B) and the venous needle; and
20 • comparing the detected value (dV) with a reference
range (I).

The present invention relates, in addition, to a
monitoring device.

According to the present invention, a device is
25 provided for monitoring the access to the
cardiovascular system of a patient undergoing an
extracorporeal treatment of blood in a machine
comprising a treatment device and an extracorporeal
circuit having an arterial branch and a venous branch,
30 the arterial branch having a first end fitted with an
arterial needle to be inserted in the vascular system
of the patient and a second end connected to an inlet
of the treatment device, and the venous branch having a
first end connected to an outlet of the treatment
35 device and a second end fitted with an venous needle to
be inserted in the vascular system of the patient,
the device being characterized in that it comprises:

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• a voltage generator for generating a potential
difference between a first point (B) of the venous
branch and a part of the machine;

• a detector for detecting the value (dV) of a quantity
5   that correlates with the electric current along at
least one section of the venous branch between the
first point (B) and the venous needle;

• calculating means for comparing the detected value
(dV) with a reference range (I).

10   The invention will now be described, with respect
to the appended drawings, in which:

• Fig. 1 is a schematic representation of a dialysis
    machine connected to a patient and equipped with a
    monitoring device according to the invention;

15   • Fig. 2 is a schematic representation of a dialysis
    machine connected to a patient and equipped with a
    variant of the device in Fig. 1; and

• Fig. 3 is a schematic representation of a dialysis
    machine connected to a patient and equipped with
20   another variant of the device in Fig. 1.

        In Figs. 1, 2 and 3, the number 1 indicates a
dialysis machine connected to a patient P. The machine
1 comprises an extracorporeal blood circuit 2 and a
dialysis fluid circuit 3 which pass through a dialyzer
25   4, which comprises a blood compartment 5 and a dialysis
compartment 6 separated by a semipermeable membrane 7.

        The extracorporeal blood circuit 2 comprises, in
addition to the compartment 5 of dialyzer 4, an
arterial branch 8, along which a peristaltic pump 9 is
30   arranged, supplying a blood flow Q_b, and a venous branch
10, to which a bubble trap 11 is connected. Arterial
branch 8 has a needle 12 which, in use, is inserted in
a fistula of patient P to collect blood from the
cardiovascular system of the patient P, while venous
35   branch 10 has a venous needle 13 which, in use, is
inserted in the fistula for returning the treated blood
to the cardiovascular system of patient P. Arterial and
venous branches 8 and 10 are tubes made of a plastic
material, generally PVC, as well as bubble trap 11.

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Dialyzer 4 is also made of plastic material, the housing of it generally of polycarbonate.

In Figs. 1, 2 and 3, machine 1 is equipped with a device 14 for detecting disconnection of needles 12 and
5   13. The principle of the device 14 is based on the electrical conductivity of the blood and on data found experimentally that showed that circuit 2 made of PVC can be regarded as an insulator and that both the peristaltic pump 9 and the bubble trap 11 can be
10   regarded as concentrated impedances designated Z1 and Z2 respectively. Peristaltic pump 9 cyclically interrupts the blood flow Q_b, at each half-turn of the pump 9 and accordingly the impedance Z1 is a function of the number of turns of pump 9 and of the supply
15   frequency. Experiments have established that the impedance Z1 is between 500 and 2000 kΩ. The impedance Z2 is determined as well by the fact that the blood flow Q_b is interrupted in the bubble trap 11 and the value assumed by Z2 is also between 500 and 2000 kΩ.
20   Recent designs of bubble trap have a relatively low impedance, which is negligible with respect to the impedance Z1. This circumstance will be borne in mind when describing the operation of device 14.

The impedances of the other components of
25   extracorporeal circuit 2 are negligible with respect to the values of impedance Z1. To evaluate the operation of device 14, it is necessary to bear in mind that the dialyzer 4 is connected to earth via the dialysis fluid circuit 3 and that the patient P may be connected to
30   earth (R = 0) or insulated (R = infinity) or in a situation intermediate between the two preceding limiting situations. These distinctions are important as it would be difficult to prevent the patient P from moving, for example resting a foot on the floor or
35   placing a hand on the bedhead of an uninsulated bed, thus altering the configuration of the possible electric circuits defined by the machine 1, the patient P, and device 14.

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        In Fig. 1, device 14 comprises a control unit 15,
    a generator 16 connected to arterial and venous
    branches 8 and 10, a detector 17 of a voltage drop and
    a clamp 18 arranged along venous branch 10. Generator
5   16 is connected respectively by two conductors 19 and
    20 and by two capacitive couplers 21 and 22
    respectively to arterial branch 8 and to venous branch
    10. Detector 17 is connected by two conductors 23 and
    24 and by two capacitive couplers 25 and 26 to venous
10 branch 10 for detecting the voltage drop along a
    predetermined section 10a of branch 10. An optimum
    filter FO is arranged along conductors 23 and 24 for
    minimizing the effect of noise on the input of detector
    17, which is connected to control unit 15 for
15 transmitting a value dV indicating the voltage drop in
    section 10a to unit 15, which compares this value with
    a threshold value dVT. If the value detected is not
    inside a range I around the threshold value dVT,
    control unit 15 emits a control signal S for stopping
20 pump 9, a control signal G for closing clamp 18 and a
    signal T for emitting a visible and/or acoustic alarm
    signal.

        Capacitive couplers 21, 22, 25 and 26 are made
    with respective metal tubes 27, which are connected to
25 the respective conductors 19, 20, 23 and 24 and are
    arranged around portions of the respective PVC tubes.
    From the electrical standpoint, tube 27 defines a first
    plate of a capacitor, the PVC tube defines the
    dielectric, and the blood inside the PVC tube defines
30 the second plate.

        Capacitive coupler 21 is arranged on arterial
    branch 8 at a point A between the arterial needle 12
    and the peristaltic pump 9, while capacitive coupling
    22 is arranged on the arterial branch 10 at point B
35 between bubble trap 11 and needle 13. Detector 17 is
    connected to venous branch 10 at points C and D, both
    of which are between point B and the venous needle 13
    and define the end of section 10a.

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When the patient is insulated (R infinite) and impedance Z2 is high, the operation of the monitoring device 14 according to the invention is as follows: the blood being circulated in the extracorporeal circuit 2
5   in the direction indicated by the arrows in Fig. 1, a potential difference is applied between venous branch 10 and arterial branch 8 by means of generator 16 and the respective capacitive couplers 21 and 22. This potential difference generates a current between a
10 section of venous branch 10 and a section of arterial branch 8 which is closed by the cardiovascular system of the patient P on account of the high impedances Z1 and Z2 on the other portion of circuit 2. Detector 17 detects the voltage drop along section 10a of arterial
15 branch 10 and stores a value indicating the voltage drop as threshold value dVT, determines the range I of acceptability around the threshold value dVT and checks whether the successive values dV are inside range I.

When one of the needles 12 and 13 accidentally
20 becomes disconnected from the fistula, the detector 17 detects the cancellation of the voltage drop dV in section 10a, and the control unit 15 emits signals S, G and T for stopping the peristaltic pump 9, closing the clamp 18, and emitting an alarm signal.

25 The monitoring device 14 is particularly advantageous because it by-passes the impedances Z1 and Z2, and the dialyzer 4 which is connected to earth. Therefore it is possible to work with relatively low currents since disconnection of one of the needles 12
30 and 13 represents an appreciable change in the current along a circuit comprising a portion of the arterial branch 8 and a portion of the venous branch 10, the conductors 19 and 20 and the cardiovascular system of the patient P.

35 .   When the patient P is connected to earth (R = 0), if the venous needle 13 becomes disconnected, there is no current flowing through the venous branch 10 and therefore detector 17 detects a voltage drop equal to zero as is the case when patient P is insulated. If the

arterial needle 12 becomes disconnected, there is a voltage drop in section 10a, which is a function of the impedance Z1 of the peristaltic pump and is therefore significant owing to the high value of impedance Z1.

5   When Z2 is negligible, disconnection of venous needle 13 is detected both when the patient is insulated (R infinite) and when he is connected to earth (R = 0), as preferential flow of current occurs along the portion of extracorporeal circuit 2 on the

10   side of patient P.

In the embodiment of Fig. 2, there is no capacitive coupler 25 since point C coincides with point B, whereas point D is located close to the venous needle 13. In this case, detector 17 detects the change

15   in voltage along a section 10b, which is a section of branch 10 between point B (i.e. C) and, essentially, the venous needle 13.

When the patient P is insulated (R infinite) and Z2 is high, the current circulates through conductors

20   19 and 20, a portion of the venous branch 10 and a portion of the arterial branch 8. Disconnection of one of the needles 12 and 13 has the effect that the voltage drop is cancelled along the section 10b and the patient P.

25   When the patient P is connected to earth (R = 0), a disconnection of the venous needle 13 causes the cancellation of the voltage drop as in the preceding case, whereas when the arterial needle 12 is disconnected, the voltage drop becomes a function of

30   the impedance Z1 as in the preceding case.

When Z2 is negligible, the considerations relating to the variant in Fig. 1 apply, except that the greater length of section 10b relative to section 10a makes it possible to refer to high values dV, at equal current

35   passing through the venous branch 10, and therefore the device 14 is more efficient, as it increases the difference between the value of the voltage drop dV determined by the condition with the venous needle 13 connected and the zero value of dV.

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According to a variant that is not shown, again the capacitive coupler 26 is omitted and is replaced with a conductive bracelet, not shown, connected directly to one wrist of the patient P. The operation
5 of the said variant that is not shown does not differ substantially from the variant in Fig. 2.

According to the variant in Fig. 3, capacitive coupling 21 to the arterial branch 8 is omitted, since generator 16 is connected to earth via conductor 19,
10 and detector 17 is connected to the venous branch 10 via conductor 23 and the capacitive coupler 25 at point C and to the arterial branch 8 via conductor 24 and the capacitive coupler 26 at a point F between the peristaltic pump 9 and arterial needle 12.

15 In use, when the patient P is insulated (R infinite) and the impedance Z2 is high, the value dV of voltage drop along section 10c of the venous branch, section 8c of the arterial branch 8, and the cardiovascular system of the patient P is detected.
20 Section 10c is between point C and arterial needle 13, whereas section 8c is between point F and venous needle 12. Disconnection of one of the needles 12 and 13 causes cancellation of the voltage drop.

When the patient P is connected to earth (R = 0),
25 a disconnection of the venous needle 13 causes the cancellation of the voltage drop, whereas a disconnection of the arterial needle 12 does not cause any appreciable change in the voltage drop dV.

When the impedance Z2 is negligible, a low current
30 will pass along section 10c, however section 10c along which the voltage drop dV is determined is relatively long and therefore a detection thereof is significant.

In practice, all the variants of the monitoring device 14 described with reference to the Figs. 1, 2
35 and 3 enable a reliable detection of the disconnection of the venous needle 13, since a disconnection of the venous needle 13 causes, both when the patient P is insulated (R infinite), and when the patient is connected to earth (R = 0), a significant change in the

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value dV of voltage drop, in comparison with the situation in which the venous needle 13 is connected.